# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF TEXAS FORT WORTH DIVISION

BAYLOR ALL SAINTS MEDICAL CENTER dba BAYLOR SCOTT & WHITE ALL SAINTS MEDICAL CENTER - FORT WORTH	) )
301 N. Washington Ave	) 6 3 4 4 4 6 4 6 6 4 2 6
Dallas, TX 75246	) Case No. 4:24-cv-00432
Dallas, 1X /3240	)
BAYLOR MEDICAL CENTER AT IRVING	)
dba BAYLOR SCOTT & WHITE MEDICAL	)
CENTER-IRVING	)
	)
301 N. Washington Ave	)
Dallas, TX 75246	)
BAYLOR MEDICAL CENTER AT	)
WAXAHACHIE	)
	)
dba BAYLOR SCOTT & WHITE MEDICAL	)
CENTER – WAXAHACHIE	)
301 N. Washington Ave	)
Dallas, TX 75246	)
DAVI OD COOTT ( WILLITE MEDICAL	)
BAYLOR SCOTT & WHITE MEDICAL	)
CENTER – CENTENNIAL	)
301 N. Washington Ave	)
Dallas, TX 75246	)
BAYLOR SCOTT & WHITE MEDICAL	)
CENTERS - GREATER NORTH TEXAS	)
dba BAYLOR SCOTT & WHITE MEDICAL	)
	)
CENTER – MCKINNEY	)
301 N. Washington Ave	)
Dallas, TX 75246	)
BAYLOR UNIVERSITY MEDICAL CENTER	)
301 N. Washington Ave	)
e	)
Dallas, TX 75246	)
COVENANT MEDICAL CENTER	)
1801 Lind Ave SW	)
Renton, WA 98057	)
Renton, WA 70037	)
EL PASO COUNTY HOSPITAL DISTRICT	,
d/b/a UNIVERSITY MEDICAL CENTER OF EL	)
PASO	)
4815 Alameda Avenue	ĺ
	,

El Paso, Texas 79905	)
HILLCREST BAPTIST MEDICAL CENTER dba BAYLOR SCOTT & WHITE MEDICAL CENTER – HILLCREST 301 N. Washington Ave Dallas, TX 75246	))))))
HUNT MEMORIAL HOSPITAL DISTRICT, dba HUNT REGIONAL HEALTHCARE 4215 Joe Ramsey Blvd Greenville, TX 75401	)))))
LAKE POINTE OPERATING COMPANY, L.L.C. dba BAYLOR SCOTT & WHITE MEDICAL CENTER - LAKE POINTE 301 N. Washington Ave Dallas, TX 75246	))))))
SCOTT & WHITE HOSPITAL - COLLEGE STATION dba BAYLOR SCOTT & WHITE MEDICAL CENTER - COLLEGE STATION 301 N. Washington Ave Dallas, TX 75246	)))))))
SCOTT & WHITE HOSPITAL - MARBLE FALLS dba BAYLOR SCOTT & WHITE MEDICAL CENTER - MARBLE FALLS 301 N. Washington Ave Dallas, TX 75246	))))))
SCOTT & WHITE MEMORIAL HOSPITAL dba BAYLOR SCOTT & WHITE MEDICAL CENTER-TEMPLE 301 N. Washington Ave Dallas, TX 75246	))))))
Plaintiffs,	)
$\nu$ .	)
XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, 200 Independence Avenue SW	) ) )

# 

Washington, DC 20201,	)
	)
Defendant.	) )

**COMPLAINT** 

#### I. INTRODUCTION

Plaintiffs are hospitals located in the State of Texas that participate in the federal Medicare program. They challenge the final decision of the Secretary of the United States Department of Health and Human Services ("the Secretary") to deny a significant portion of their Medicare disproportionate share hospital ("DSH") payments. DSH payments are a statutorily-required supplemental payment to Medicare hospitals that help offset the cost of providing care to large numbers of low-income Medicare and Medicaid-eligible individuals. The Secretary announced his decision in a regulation, effective October 1, 2023, that permanently reduces the Plaintiff hospitals' Medicare DSH payments in Federal Fiscal Year ("FFY") 2024. This new regulation immediately imposes two adverse impacts on Plaintiffs and other DSH hospitals in Texas. First, it reduces their DSH payments by excluding individuals who are not traditionally eligible for Medicaid, but whom the Secretary deemed to be Medicaid-eligible when he approved a Texas Medicaid waiver that helped pay for their inpatient care. Second, it denies them access to the federal 340B drug discount program, which Congress adopted to assist safety-net hospitals combat the high cost of drugs. See 42 U.S.C. § 256b(a)(4)(L). Further, the Secretary's new regulation unfairly targets DSH hospitals in states, like Texas, that have elected to provide Medicaid-like benefits to uninsured individuals through uncompensated care pools rather than expand traditional Medicaid benefits to the same population.

The Secretary's new regulation is in direct conflict with the Medicare statute, which requires him to credit such individuals in the Plaintiff hospitals' Medicare DSH payments. *See* 42 U.S.C. § 1395ww(d)(5)(F). Indeed, the United States Court of Appeals for the Fifth Circuit has already held that the Medicare statute requires the Secretary to make Medicare DSH payments attributable to individuals he deemed to be Medicaid-eligible when he approved a Medicaid state waiver that grants them Medicaid-like benefits. *Forrest General Hosp. v. Azar*, 926 F.3d 221,

228–29 (5th Cir. 2019); see also Bethesda Health, Inc. v. Azar, 389 F. Supp. 3d 32, 47 (D.D.C. 2019) (favorably citing the Fifth Circuit's interpretation of the statute in Forrest General), aff'd, 980 F.3d 121 (D.C. Cir. 2020).

To make matters worse, the Secretary has attempted to delay the Plaintiff hospitals' federal court challenge to his unlawful regulation, manufacturing a reason to push the day of reckoning back by several years. Hospitals that are dissatisfied with the Secretary's "final" payment decisions must first seek relief from the Provider Reimbursement Review Board ("PRRB" or "the Board"). 42 U.S.C. § 139500. In this case, the Board, acting on behalf of the Secretary, wrongfully dismissed Plaintiff hospitals' appeals. Plaintiff hospitals also bring this action to challenge the Board's decision to dismiss their appeals.

The Secretary's actions will cause the Plaintiff hospitals immediate and irreparable harm. The Secretary's DSH payment cuts have significantly reduced their Medicare reimbursement for FFY 2024 and beyond and force the Plaintiff hospitals to limit services and immediately undertake other cost-cutting measures in the short term. The service limitations and cost-cutting measures will be even more severe for those Plaintiff hospitals that will experience steep price increases for outpatient drugs in FFY 2024 and beyond when they no longer qualify for 340B discounts due to the Secretary's new regulation. For these reasons, Plaintiff hospitals seek entry of an order from this Court: (1) reversing the Board's decision to dismiss their administrative appeals and retaining jurisdiction to review Plaintiff hospitals' challenge to the Secretary's new DSH regulation; (2) vacating the Secretary's new DSH regulation because it is arbitrary and capricious and contrary to law; and (3) permanently enjoining the Secretary from implementing his new DSH regulation in FFY 2024 and beyond.

Plaintiff hospitals allege the following in support of their claims and request for relief.

#### II. PARTIES

- 1. Plaintiffs are several hospitals in the State of Texas that participate in the Medicare Program. Many of the Plaintiff hospitals also participate in the federal 340B Drug Pricing Program as DSH hospitals. The Plaintiff hospitals are listed below with their Medicare provider numbers:
  - (a) Baylor All Saints Medical Center dba Baylor Scott & White All Saints Medical Center Fort Worth, Medicare Provider No. 45-0137;
  - (b) Baylor Medical Center at Irving dba Baylor Scott & White Medical Center-Irving, Medicare Provider No. 45-0079;
  - (c) Baylor Medical Center at Waxahachie dba Baylor Scott & White Medical Center Waxahachie, Medicare Provider No. 45-0372;
  - (d) Baylor Scott & White Medical Center Centennial, Medicare Provider No. 45-0885;
  - (e) Baylor Scott & White Medical Centers Greater North Texas dba Baylor Scott & White Medical Center McKinney, Medicare Provider No. 67-0082;
  - (f) Baylor University Medical Center, Medicare Provider No. 45-0021;
  - (g) Covenant Medical Center, Medicare Provider No. 45-0040;
  - (h) El Paso County Hospital District d/b/a University Medical Center of El Paso, Medicare Provider No. 45-0024;
  - (i) Hillcrest Baptist Medical Center dba Baylor Scott & White Medical Center Hillcrest, Medicare Provider No. 45-0101;
  - (j) Hunt Memorial Hospital District, dba Hunt Regional Healthcare, Medicare Provider No. 45-0352;

- (k) Lake Pointe Operating Company, L.L.C. dba Baylor Scott & White Medical Center - Lake Pointe, Medicare Provider No. 45-0742;
- Scott & White Hospital College Station dba Baylor Scott & White
   Medical Center College Station, Medicare Provider No. 67-0088;
- (m) Scott & White Hospital Marble Falls dba Baylor Scott & White Medical

  Center Marble Falls, Medicare Provider No. 67-0108; and
- (n) Scott & White Memorial Hospital dba Baylor Scott & White Medical Center-Temple, Medicare Provider No. 45-0054.
- 2. The Defendant, Xavier Becerra, is the Secretary of HHS, which administers the Medicare and Medicaid programs established under titles XVIII and XIX of the Social Security Act. Defendant Becerra is sued in his official capacity only. The Centers for Medicare & Medicaid Services ("CMS") is the federal agency to which the Secretary has delegated administrative authority over the Medicare and Medicaid programs. References to the Secretary herein are meant to refer to him, his subordinate agencies and officials, and to his official predecessors or successors as the context requires.

#### III. JURISDICTION AND VENUE

- 3. The Plaintiff hospitals' Medicare reimbursement claims arise under the Medicare statute, title XVIII of the Social Security Act, 42 U.S.C § 1395 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* The Plaintiffs' 340B drug discount claims arise under the Public Health and Safety Act, *see* 42 U.S.C. § 256b(a)(4)(L), and the Administrative Procedure Act, *supra*.
  - 4. Jurisdiction is proper under 42 U.S.C. § 139500(f)(1) and 28 U.S.C. § 1331.
- 5. Venue is proper in this judicial district under 42 U.S.C. § 139500(f)(1) because, "in an action brought jointly by several providers," this judicial district is the one "in which the greatest

number of such providers are located...." Venue is also proper in this judicial district under 28 U.S.C. § 1391.

#### IV. BACKGROUND

# A. The Medicare DSH adjustment

- 6. The Medicare program, established as title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, is a federal entitlement program that provides healthcare insurance to the nation's aged and disabled. Medicare Part A entitles beneficiaries to payment for inpatient hospital services and other institutional health care services such as skilled nursing facility services and home health care services. Medicare Part B entitles beneficiaries to payment for physician and other medical services such as clinical diagnostic laboratory testing and other diagnostic services.
- 7. Prior to 1983, the Medicare program reimbursed hospitals for the actual costs they incurred when providing inpatient care to Medicare beneficiaries. Congress determined, however, that reimbursing hospitals on a cost basis did not incentivize hospitals to lower costs and seek efficiencies in providing care. Since 1983, hospitals have instead been reimbursed for the inpatient services they provide Medicare beneficiaries pursuant to an inpatient prospective payment system ("IPPS").
- 8. Established under subsection 1886(d) of the Social Security Act, the IPPS reimburses hospitals a fixed payment amount for each hospital patient upon their discharge. The unit of fixed payment is referred to as a diagnostic related-group ("DRG"). The Medicare program recognizes hundreds of DRGs, each of which corresponds to a group of related diagnoses with a separate payment rate. 42 U.S.C. § 1395ww(d). For example, patients with pneumonia diagnoses are grouped to a single DRG that has a standardized payment rate. Patients who are admitted for a hip replacement are grouped to a different DRG with a different payment rate.

- 9. The Secretary determines the final payment rate for each DRG in advance of each fiscal year by applying a formula set forth in the Medicare statute that ties the rate for each DRG to the relative number of resources needed to treat the diagnoses grouped to that DRG. *Id.* Hospitals will then be reimbursed the applicable fixed DRG payment amount for each Medicare inpatient they treat in the forthcoming fiscal year regardless of the patient's length of stay. By setting prospectively determined, fixed rates for hospital care, Congress intended to incentivize hospitals to seek efficiencies and lower the cost of care. In order to do so, hospitals project the total amount of Medicare reimbursement they will receive each year, relying upon the Secretary's prospectively determined rates, and they budget accordingly.
- 10. In 1986, Congress amended title XVIII of the Social Security Act to require the Secretary to supplement the DRG rates for hospitals that serve "a significantly disproportionate number of low-income patients ...." 42 U.S.C. § 1395ww(d)(5)(F)(i)(I). Congress mandated these supplemental payments so that the Medicare program would pay its share of the increased costs that comes with treating low-income patients. A hospital is determined to be eligible for "disproportionate share" payments based on the calculation of a "disproportionate share" or "DSH" percentage which serves as a proxy for the number of low-income patients a hospital serves. 42 U.S.C. §§ 1395ww(d)(5)(F)(v) and (vi).
- 11. Each hospital's DSH percentage must be calculated pursuant to a precise formula set forth in the Medicare statute. The formula is based upon two fractions—or ratios—which are then added together to determine the hospital's DSH percentage. The DRG payment rates announced at the beginning of each fiscal year are increased by each hospital's DSH percentage to determine the final payment rate the hospital will receive for each discharge in that fiscal year. For example, if the unadjusted payment rate for a DRG is \$5,000 and a hospital has a DSH

percentage of 20 percent, the hospital will receive a payment rate of \$6,000 for that DRG ([\$5,000 x .20 = \$1,000] + \$5,000 = \$6,000).

- 12. Each hospital has a unique DSH percentage based upon the demographics of its inpatient population. The first fraction of the DSH percentage, commonly known as the "SSI fraction," determines the ratio of the number of hospital days applicable to individuals who are entitled to benefits under Medicare Part A (the denominator) and the number of hospital days attributable to individuals who are entitled to both Medicare Part A and Supplemental Security Income ("SSI") benefits (the numerator).
- 13. The second fraction, commonly known as the "Medicaid" fraction, determines the ratio of the number of patient days attributable to Medicaid-eligible individuals (the numerator) to the number of inpatient days attributable to all hospital inpatients (the denominator). The statutory formula for the Medicaid fraction is set forth in the following language:
  - (II) The fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consists of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, but who were not entitled to benefits under part A of this title, and the denominator of which is the total number of the hospital's patient days for such period.
- 42 U.S.C. § 1395ww(d)(5)(F)(vi) (emphasis added). The phrase "eligible for medical assistance under a State plan approved under subchapter XIX" essentially means a patient who is eligible for Medicaid.
- 14. The Plaintiff hospitals in this case challenge a regulation adopted by the Secretary that excludes from the numerator of the Medicaid fraction a large number of patients the Secretary has previously deemed to be Medicaid-eligible.

### **B.** Section 1115 Medicaid Waivers

- 15. The Medicaid program, established as part of title XIX of the Social Security Act, 42 U.S.C. § 1396 *et seq.*, is a federal entitlement program that provides "medical assistance" to certain categories of low-income individuals. The federal Medicaid program is operated as a joint federal-state partnership under which Congress has appropriated funds for the Secretary to match a participating State's expenditures for "medical assistance." 42 U.S.C. § 1396a *et seq.*
- 16. In order to receive federal matching funds, states participating in the federal Medicaid program must receive the Secretary's approval of a state plan which must include certain statutorily-defined categories of individuals—commonly referred to as "Medicaid eligibility" categories. These categories include low-income aged, blind, disabled and pregnant individuals. 42 U.S.C. § 1396d(a). A state plan must also provide these Medicaid-eligible individuals with "medical assistance," which is defined as "payment" for certain specified categories of health care services, including inpatient hospital services and physician services. *Id*.
- 17. Pursuant to section 1115 of the Social Security Act, the Secretary may waive compliance with the statutory eligibility and medical assistance requirements in order to carry out "experimental, pilot, or demonstration" projects that promote the objectives of the Medicaid program. 42 U.S.C. § 1315(a). The objectives of the Medicaid program are to provide healthcare services to low-income individuals to improve their health outcomes. To achieve these objectives, the Secretary may, for example, waive certain eligibility requirements and authorize states to expand the group of Medicaid-eligible individuals to whom they provide "medical assistance" beyond the mandatory Medicaid-eligible categories identified in the statute. The individuals who receive this benefit are often referred to as "expansion," "demonstration" or "waiver" populations, and typically they are also low-income.

- 18. By operation of 42 U.S.C. § 1315(a), when the Secretary approves a section 1115 waiver that confers benefits upon waiver populations, he also has elected to regard the costs of such projects as "medical assistance" expenditures under the Medicaid statute even though the "costs of such project … would not otherwise be included as expenditures under" the Medicaid program and, therefore, are not eligible for Medicaid matching funds. *Id*.
- 19. Subject to the Secretary's approval, section 1115 allows states to experiment with different mechanisms for providing "medical assistance" to demonstration populations. States can, for example, expand the categories of individuals who may enroll in the State's Medicaid health plans. But some States chose not to do so, and the Secretary has approved section 1115 waivers in those States under which demonstration populations receive medical assistance in other forms. Since 2005, for example, the Secretary has approved section 1115 waivers in several states, including Texas, pursuant to which the state Medicaid programs provide medical assistance in the form of direct payments to hospitals to cover the cost of inpatient care for uninsured individuals and those who receive charity care. These payments are made from uncompensated care ("UCC") pools authorized by the Secretary and recognized by him as providing the benefit of "medical assistance" to the uninsured and charity care populations. In order to approve these UCC pools, the Secretary must assure himself that they further the objectives of the Medicaid program.
- 20. The Secretary has approved the Texas Healthcare Transformation and Quality Improvement Program pursuant to section 1115 (a)(2) of the Social Security Act, which provides medical assistance benefits in the manner described in the preceding paragraph. Pursuant to the Healthcare Transformation and Quality Improvement Program, the Texas Medicaid program makes payments to hospitals from a UCC pool of dollars (matched by the Secretary) which, under the terms of the demonstration waiver, is intended to cover the cost of care provided to uninsured

patients who receive some or all of their inpatient hospital services free of charge under the hospital's charity care policy. Exhibit 1 (Texas Healthcare Transformation and Quality Improvement Program) at 52–55.

# C. The Deficit Reduction Act of 2005

- Although the Secretary matches the Medicaid expenditures incurred by States to provide medical assistance to section 1115 waiver populations, for several years the Secretary refused to count such individuals as "Medicaid-eligible" when calculating a hospital's Medicare DSH percentage. According to the Secretary, the inpatient days for such individuals could not be counted in the numerator of the Medicaid fraction because they were not "eligible for medical assistance *under a State plan approved under subchapter XIX.*" 42 U.S.C. § 1395ww(d)(5)(F)(iv)(II) (emphasis added). The Secretary claimed that he was prohibited by statute from including waiver populations in the numerator of the Medicaid fraction because they were only made eligible for medical assistance pursuant to a waiver he approved under Title XI, not a State plan.
- 22. In 2000, however, the Secretary reversed his interpretation of the Medicare DSH statute and adopted a regulation to include the inpatient days of Medicaid waiver populations in the numerator of the Medicaid fraction. Pursuant to that regulation, individuals are also considered "eligible for Medicaid ... if the patient is eligible for inpatient hospital services under an approved State Medicaid plan *or under a waiver authorized under section 1115(a)(2)* of the [Social Security] Act" 42 C.F.R. § 412.106(b)(4)(i)–(ii) (2022) (emphasis added).
- 23. However, the Secretary refused to apply his new interpretation to Medicare DSH payments before 2000. Numerous hospitals challenged the Secretary's refusal. Several courts ruled in their favor, holding that the Secretary could not rationally explain his position that the

statutory language setting forth the Medicaid fraction formula precluded him from treating section 1115 waiver populations as "eligible ... under a State plan" prior to 2000 but somehow this same language granted him the discretion to deem them to be "Medicaid-eligible" after 2000. *Portland Adventist Med. Ctr. v. Thompson*, 399 F.3d 1091, 1093 (9th Cir. 2005); *see also Cookeville Reg'l Med. Ctr. v. Leavitt*, 531 F.3d 844, 845 (D.C. Cir. 2008) ("Despite not meeting the requirements of [Title] XIX, the costs of providing care under a demonstration project are treated as federally reimbursable expenditures made under [Title XIX] 'to the extent and for the period prescribed by the Secretary." (quoting 42 U.S.C. § 1315(a)(2)(A))).

24. In the Deficit Reduction Act ("DRA") of 2005, Pub. L. No. 109-171, 120 Stat. 4, Congress amended the Medicare DSH statute to approve the Secretary's policy change and insulate the Medicare program from any further liability for Medicare payments prior to 2000. In doing so, Congress gave the Secretary explicit commands as to how to treat Medicaid waiver populations when calculating Medicare DSH payments. Congress first added statutory language that required the Secretary to treat section 1115 waiver populations as "Medicaid-eligible" once he exercised his discretionary authority to approve a section 1115 waiver. Congress then made this statutory change effective at the time it passed the Medicare DSH statute in 1986. The DRA of 2005 added the following language to the Medicaid fraction formula:

In determining under subclause (II) the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, *include patient days* of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

Pub. L. No. 109-171, § 5002, 120 Stat. at 31 (emphasis added).

25. The DRA of 2005 makes clear that section 1115 waiver populations are not "eligible for medical assistance under a State plan." But it also makes clear that, if the Secretary

exercises his authority under section 1115 and approves a waiver that extends "benefits" to such individuals, he has "regarded them" as "eligible under a State Plan," and he must include their patient days in the numerator of the Medicaid fraction. *Forrest General*, 926 F.3d at 228–29; *Bethesda Health*, 389 F. Supp. 3d at 47.

- Despite this explicit statutory command, the Secretary did not include *all* waiver populations in the Medicaid fraction numerator after 2005. For example, in 2005 the Secretary approved a section 1115 waiver for the State of Mississippi which, in relevant part, created a UCC pool to pay for the costs of inpatient hospital care provided to uninsured individuals who were displaced by Hurricane Katrina. In 2006, the Secretary approved a state Medicaid waiver for the State of Florida, which expanded medical assistance benefits to uninsured individuals. These benefits took the form of payments made to Florida hospitals from a Low Income Pool ("LIP") that was created by the State (and approved by the Secretary) to cover the cost of inpatient hospital services to uninsured individuals who received services at those hospitals. Even though the Secretary "regarded" these uninsured individuals as "eligible" for Medicaid when he approved the waiver and extended them benefits by means of UCC payments to cover their inpatient care, the Secretary refused to allow Mississippi and Florida hospitals to count their inpatient hospital days in the numerator of the Medicaid fraction for purposes of calculating their Medicare DSH payments.
- 27. Again, hospitals challenged the Secretary's decision to reduce their Medicare DSH payments, this time by excluding patient days attributable to individuals who receive benefits through section 1115 UCC pool payments. And again, several courts held that the Secretary's policy violated the plain language of the Medicare statute, specifically Congress's mandate in the DRA of 2005 that the Secretary must include patient days of individuals who are not eligible under

a State plan, but whom he "regards as such" by approving benefits under a section 1115 waiver. For example, the Fifth Circuit set aside the Secretary's decision to exclude patient days attributable to patients for whom hospitals received UCC pool payments. *See Forrest General*, 926 F.3d at 228 ("[I]f the Secretary approves a demonstration project, then we regard patient days involving inpatients who 'receive benefits under a demonstration project' as if they were patient days attributable to Medicaid-eligible patients (which means those days also go into the numerator)."). The D.C. Circuit reached a similar decision regarding the Secretary's decision to exclude patient days attributable to Florida LIP payments. *Bethesda Health*, 980 F.3d at 122.

- After the D.C. Circuit decision in *Bethesda Health*, the Secretary acquiesced to these judicial decisions on a national basis. In States where the Secretary approved a section 1115 Medicaid waiver that created UCC pools to pay for the cost of inpatient care provided to uninsured and charity care patients—including the State of Texas—the Secretary has retroactively made Medicare DSH payments to hospitals that include the patient days attributable to uninsured and charity patients in the numerator of their Medicaid fractions. Each of the Plaintiff hospitals has received Medicare DSH payments that include such patient days for Medicare DSH payments that predate FFY 2024.
- 29. The federal 340B drug discount program permits certain covered entities to purchase outpatient drugs at discounted prices, significantly reducing the costs of pharmaceuticals and enabling these hospitals to expand care to uninsured individuals. Medicare DSH hospitals with a DSH percentage of 11.75 or more (or 8 percent or more in the case of rural referral centers) qualify as 340B covered entities which can purchase discounted drugs. 42 U.S.C. § 256b(a)(4)(L). Many hospitals in Texas and other states that provide Medicaid benefits through Section 1115 uncompensated care pools are able to maintain qualifying DSH percentages solely because they

can include the patient days of uninsured and charity patients in the numerator of the Medicaid fraction.

#### D. The FY 2024 Final DSH Rule

- 30. In August 2023, the Secretary adopted a new regulation—effective October 1, 2023 and beyond—that expressly excludes from the Medicaid numerator patients who have received inpatient hospital benefits through section 1115 UCC pool payments approved by the Secretary. The new regulation, promulgated at 42 C.F.R. § 412.106(b)(4)(iii), is in direct conflict with the law of the Fifth Circuit. Even though the language of the DRA of 2005 amendment is clear that the Secretary must count *all* individuals who receive benefits through an approved section 1115 wavier, the Secretary's rule is premised on the misguided belief that he has unfettered discretion to include certain waiver populations and exclude others. The Fifth Circuit has already rejected this interpretation as contrary to the plain language of the Medicare statute. *Forrest General*, 926 F.3d at 228–29.
- The Secretary is well aware that his new rule conflicts with the Medicare statute. He first proposed a similar regulation in 2021, to be effective in FY 2022, but he did not finalize the rule due to opposition from hospital providers in Texas and other affected states. And again in 2022, he proposed a slightly modified version of the 2021 proposal to be effective for FY 2023. But again, the Secretary did not finalize the proposal in response to opposition from hospital providers. The Secretary eventually adopted the current version of his new DSH regulation even though hospital providers continued to explain in comments that several courts—including the Fifth Circuit—had previously rejected the Secretary's interpretation of the Medicare DSH statute upon which he was relying to promulgate the new rule.
- 32. The Secretary's new regulation targets individuals who receive medical assistance in the form of payments from UCC funding pools with the following language:

Patients whose health care costs, including inpatient hospital services costs, for a given day are claimed for payment by a provider from an uncompensated, undercompensated, or other type of funding pool authorized under section 1115(a) of the Act to fund providers' uncompensated care costs are not regarded as eligible for Medicaid for purposes of paragraph (b)(4)(ii) of this section on that day and the days of such patients may not be included in this second computation.

42 C.F.R. § 412.106(b)(4)(iii); 88 Fed. Reg. 58,640, 59,332 (Aug. 28, 2023).

- 33. With new clause (b)(4)(iii), the Secretary has declared, contrary to law, that he chooses not to "regard[]" individuals who receive inpatient benefits by means of a section 1115 UCC pool as "eligible for Medicaid." Thus, he has made a *final determination* to exclude their inpatient days from the numerator of the Medicaid fraction. 88 Fed. Reg. at 59,332.
- 34. Federal courts have already found the Secretary's prior attempts to limit the inclusion of section 1115 UCC days in the Medicaid fraction as a violation of the Medicare statute, and (b)(4)(iii) is no exception. The Secretary relied upon the same interpretation of the DRA of 2005 in defense of his position in *Forrest General*. In plain and direct language, the Fifth Circuit held that this theory was unsupported by the language of the Medicare statute:

Put bluntly: Certain days just go into the Medicaid fraction's numerator. Which days? Days that a hospital treated Medicaid-eligible patients or — if the Secretary approves a demonstration project — patients regarded as Medicaid eligible because of a demonstration project. This is binary: Patient days are either in or out. If patients underlying a given day were Medicaid-eligible or "receive[d] benefits under a demonstration project," then that day goes into the numerator.

Forrest General, 926 F.3d at 228–29; see also Bethesda Health, 389 F. Supp. 3d at 47 (favorably citing the Fifth Circuit's interpretation of the statute in Forrest General).

35. The Secretary's new regulation runs directly counter to the stated reason why Congress mandated that the Secretary provide supplemental Medicare DSH payments. The 1986 amendments to the Medicare statute reflect Congress's recognition that "[h]ospitals that serve a disproportionate share of low-income patients have higher [M]edicare costs per case[,]" H.R. Rep. No. 99-241, pt. 1, at 16 (1985), and that those higher costs would not otherwise be compensated

by the IPPS DRG rate formula. Instead, the Secretary now contravenes the Medicare statute by denying Plaintiff hospitals all Medicare DSH reimbursement attributable to claiming large numbers of low-income individuals as "Medicaid eligible." What is more, the Secretary adopted his new regulation even though he has already been ordered by courts (several times) that the Medicare statute does not afford the Secretary the discretion to exclude certain patients once he has conferred a benefit upon them by approving a section 1115 waiver. *See Forrest General*, 926 F.3d at 233 ("Once the Secretary authorizes a demonstration project, no take-backs.").

36. When reminded of the Fifth Circuit's holding during notice and comment rulemaking, the Secretary offered no explanation as to why his new regulation is consistent with *Forrest General*. Instead, the Secretary brushed aside the Fifth Circuit's holding and stated that he considers his interpretation of the statute "the better reading." 88 Fed. Reg. at 59,020.

#### E. The Provider Reimbursement Review Board

- 37. In order to challenge a final payment determination like the Secretary's new regulation, hospital providers like the Plaintiff hospitals must first bring their challenge to the Provider Reimbursement Review Board. The Board's authority to grant a provider a hearing—its jurisdiction—is set forth in section 1878 of the Social Security Act.
- 38. There are three statutory prerequisites for the Board to exercise jurisdiction over a Medicare hospital appeal. The hospital must be dissatisfied with a "final" Medicare payment determination. The appeal must be filed within 180 days of the final payment determination. The appeal must also meet the statutory amount in controversy requirements. 42 U.S.C. § 1395oo(a)(1).
- 39. Congress has granted providers the right to appeal two types of "final" Medicare payment determinations. First, the Medicare program requires hospitals submit a cost report at the end of each fiscal year, which sets forth the amount of Medicare reimbursement claimed by the

hospital for the past year. Those costs reports are reviewed by the Secretary's fiscal intermediaries who, following their review, issue a "final payment determination." Providers have a right to a hearing over this type of final payment determination. *Id.* § 139500(a)(1)(A)(i).

- 40. After Congress adopted the IPPS, Congress granted Medicare hospitals the right to appeal from another "final" payment determination that was not connected with the filing of a year-end cost report. Because the IPPS system sets prospectively determined rates at the beginning of each fiscal year, which hospitals must use for budgetary reasons, Congress recognized that the Secretary may make errors in determining those rates and that it would be unfair to require hospitals to wait several months, sometimes years, until the resolution of their cost reports before seeking administrative and judicial review. Therefore, Congress amended the Social Security Act to give the Board jurisdiction over appeals where hospital providers are "dissatisfied with a final payment determination of the Secretary as to the amount of ... payment under subsection ... (d)." *Id.* § 139500(a)(1)(A)(ii). Subsection (d) establishes the IPPS system, including the formulae for determining supplemental Medicare DSH payments. Providers are not required to wait for a cost report settlement before appealing a final payment determination under subsection (d).
- 41. The Secretary announces his IPPS final rate determinations in the Federal Register before the beginning of the federal fiscal year. Courts have uniformly held that these Federal Register publications constitute "final payment determinations of the Secretary" from which an immediate appeal to the Board may be taken under 42 U.S.C. § 139500(a)(1)(A)(ii). *Wash. Hosp. Ctr. v. Bowen*, 795 F.2d 139, 148 (D.C. Cir. 1986) (holding that any administrative action that provides "advance knowledge of the amount of payment [a provider] will receive" is a "final determination" of the Secretary.").

- 42. Providers "have the right to obtain judicial review of any final decision of the Board ...." 42 U.S.C. § 1395oo(f)(1). A Board dismissal decision is a "final decision" and subject to judicial review. 42 C.F.R. §§ 405.1877(a)(3)(i), 405.1875(a)(2)(ii); see also Lee Mem'l Hosp. v. Becerra, 10 F.4th 859, 865 (D.C. Cir. 2021) ("There is no dispute that the Board's administrative dismissals were 'final decisions' on appellants' claims, which, at a minimum, conferred jurisdiction in the district court to review those dismissals.")
- 43. Additionally, in 1980, Congress added another provision to the Medicare statute which allowed hospitals to seek Expedited Judicial Review ("EJR") in cases where the Board has jurisdiction under the statute to hear a hospital's appeal but lacks the authority to grant the hospital the relief requested. Specifically, the Board is bound to follow all statutes, regulations, and agency policies. 42 U.S.C. § 139500(f)(1); 42 C.F.R. § 405.1842. When a hospital provider seeks to have one of those provisions set aside as unlawful, the Board instead must grant EJR of the appeal so that the provider may immediately elevate its challenge to federal district court. 42 U.S.C. § 139500(f)(1); 42 C.F.R. § 405.1842.

#### V. PROCEDURAL HISTORY

44. Pursuant to 42 U.S.C. § 139500, the Plaintiff hospitals have challenged, and are dissatisfied with, the Secretary's final payment determination to deny Plaintiff hospitals' Medicare DSH payments attributable to the inpatient days of individuals whose inpatient hospital services were eligible to be covered in whole or in part by a UCC pool established under a section 1115 waiver approved by the Secretary. The Plaintiff hospitals presented their claims to the Secretary in the form of timely filed appeals with the Board within 180 days of the Federal Register publication of the FY 2024 Final Rule in which the Secretary finalized his new DSH regulation. Plaintiff hospitals' appeals satisfy all other jurisdictional requirements for an appeal set forth at 42 U.S.C. § 139500(a)–(b). Below is a list of the following group appeals at issue:

Group Case Name	<b>Group Case No.</b>
BS&W Health FFY 2024 § 1115 Waiver Days Texas CIRP Group	24-1591GC
King & Spalding FFY 2024 § 1115 Waiver Days Texas III Group	24-1595G

- 45. On March 11, 2024, the Board issued a decision revealing that it *sua sponte* reviewed the above appeals and found that it lacked jurisdiction over the Plaintiff hospitals' appeals and dismissed the appeals with prejudice. Exhibit 2 (Board Dismissal). The Board did so before the Plaintiff hospitals could seek EJR.
- 46. The Board erroneously determined that the Secretary's new Medicare DSH regulation was not an "appealable final determination" because it "impacts one of many variables in calculating the Provider's [sic] DSH payment ...." Exhibit 2 at 18. The Board further held that Plaintiff hospitals would not receive a "final payment" determination until such time as they filed year-end cost reports, those cost reports were reviewed by the Secretary's intermediaries (the MACs) and the supplemental Medicare DSH payments they received throughout the fiscal year were reconciled when the MACs settled their cost reports. Under the Board's reasoning, even though the Secretary has already determined as of October 1, 2023 that the Plaintiff hospitals will receive no Medicare DSH payments associated with individuals who receive benefits through section 1115 UCC pool payments, the Plaintiff hospitals must wait several years and until such time as the Secretary's intermediaries make a second determination that they are entitled to no Medicare DSH payments attributable to these waiver populations.
- 47. The Board relied upon *Memorial Hospital of South Bend v. Becerra*, No. CV 20-3461, 2022 WL 888190 (D.D.C. Mar. 25, 2022) in its decision dismissing the Plaintiff hospitals' appeals. Exhibit 2 at 17. The Secretary periodically publishes every DSH hospital's SSI ratio—the other ratio that makes up a hospital's DSH percentage—but makes clear that these ratios are

subject to change. The court in *Memorial Hospital* held that the publication of these SSI ratios was not "final" and therefore not appealable to the Board. The Board ignored, however, that the court in *Memorial Hospital* distinguished the publication of SSI ratios from a "clearly promulgated as a final rule" that affects a hospital's total Medicare payment. 2022 WL 888190, at \*8. Moreover, the Board's decision wholly disregarded the D.C. District Court's more recent opinion in *Battle Creek Health Sys. v. Becerra* that reached the opposite conclusion as to whether the publication of SSI ratios is appealable. No. 17-0545, 2023 WL 7156125 (D.D.C. Oct. 31, 2023). The Board stated it "disagrees with *the Battle* Creek decision and maintains that *Memorial Hospital* is a better-reasoned decision...." Exhibit 2 at 17 n.68. In addition to this flawed reasoning, the Board's decision also ignores the fact that the Secretary's final payment determination set forth in his new DSH regulation was announced in a "clearly promulgated" *final* rule that was intended to establish final Medicare payment rates. Even the *Memorial Hospital* court recognized a final rule of this nature would be distinct from the publication of temporary SSI ratios. 2022 WL 888190, at \*8.

48. The Board also identified "factual gaps" that it believed prevented it from determining whether it had jurisdiction over the appeals. For example, the Board stated that it could not confirm from the Plaintiff hospitals' appeals whether Texas has a section 1115 waiver with a UCC pool or whether Plaintiffs collectively could meet the \$50,000 amount in controversy requirement (under the theory that their Medicare DSH payments are not final until after the end of the fiscal year). Exhibit 2 at 19. If, in fact, the Board genuinely believed that additional information was necessary for it to determine jurisdiction, then its own rules required it to allow the Plaintiff hospitals to address any alleged "factual gaps." 42 C.F.R. § 405.1842(e)(3)(ii). The Board's alleged factual gaps are merely pretextual, however.

- The Board's dismissal is wrong on the merits. The Secretary's clearly promulgated regulation is unquestionably a final payment determination because it informs the Plaintiff hospitals at the beginning of the FFY that they will receive reduced Medicare DSH payment amounts in FY 2024. Specifically, because the new regulation fixes (at zero) the amount of additional Medicare DSH reimbursement, the Plaintiff hospitals know today the exact amount of Medicare DSH payments they will receive for treating patients covered by the UCC pool authorized by the Texas section 1115 waiver—zero. Because the new regulation sets that payment amount, it is a final payment determination of the Secretary that can be appealed under 42 U.S.C. § 1395oo(a)(1)(A)(ii).
- 50. The Secretary's regulation unfairly targets hospitals in States, like Texas, that have elected to provide Medicaid benefits in the form of uncompensated care pool payments under a Medicaid 1115 waiver. The Secretary's regulation prohibits those hospitals from including days attributable to uninsured and charity care individuals in the numerator of the Medicaid fraction, thereby lowering all DHS hospitals' Medicare reimbursement (in some cases, eliminating it entirely) and disqualifying many hospitals in these States from the 340B drug discount program. Meanwhile, the Secretary's regulation has no such impact on hospitals in States that elected to expand the categories of individuals who could be enrolled into the State's Medicaid program under a section 1115 waiver. These individuals, according to the Secretary are "regarded as" Medicaid-eligible while the uninsured and charity care individuals who receive uncompensated care pool benefits are not.
- 51. Because the Board's decision to dismiss the group appeals is the "final decision of the Board," 42 U.S.C. § 139500(f)(1), the Plaintiff hospitals now timely appeal to this Court.

#### VI. CAUSES OF ACTION

#### **COUNT ONE**

#### (Provider Reimbursement Review Board Dismissal)

(Violations of the Administrative Procedure Act and Medicare Statute)

- 52. The allegations set forth in paragraphs 1 through 51 are incorporated by reference as if fully set forth herein.
- Pursuant to 42 U.S.C. § 139500(a)(1)(A)(ii), a hospital provider may obtain a hearing with the Board if such provider "is dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1886" of the Social Security Act. Subsection (d) of 1886 establishes the IPPS payment formula, including the Medicare DSH payment formula that is at issue in this case. Congress adopted § 1395(a)(1)(A)(ii) to allow hospital providers to appeal the Secretary's final payment determinations established in the fiscal year IPPS payment rule immediately. *Wash. Hosp.*, 795 F.2d at 146 ("[T]he appeals provisions applicable to PPS recipients cannot be read to require hospitals to file cost reports and await [final notices of program reimbursement] prior to filing a PRRB appeal.").
- 54. The Board's final decision dismissing Plaintiff hospitals' appeals is arbitrary and capricious and contrary to the plain meaning of the Medicare statute. The Secretary's new regulation is a "final payment determination" under subsection 1886(d) of the Secretary's decision to deny Plaintiff hospitals Medicare DSH reimbursement attributable to individuals whose inpatient care is covered by payments from a section 1115 UCC pool approved by the Secretary. In addition, the Board's decision is arbitrary and capricious and cannot be supported with a rational explanation. The Board reasoned that, in order for the Secretary's payment determination to be "final," it is necessary for the Plaintiff hospitals to first receive lower Medicare DSH payments throughout FY 2024, file a cost report several months after the expiration of FY 2024 and wait several more months (perhaps years) for the Secretary's contractors to review and settle the FY

2024 cost report. But filing a cost report and waiting for the Secretary's contractors to review and settle that cost report many years from now will not alter the final payment result—the Secretary's contractors are bound by his regulation, and they must conclude on the cost report that the Plaintiff hospitals can receive no Medicare DSH reimbursement for treating individuals whose care is covered by section 1115 UCC pool payments.

55. For the reasons explained above, the Board's dismissal was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

# COUNT TWO (Secretary's Final DSH Regulation)

(Violations of the Administrative Procedure Act and Medicare Statute)

- 56. The allegations set forth in paragraphs 1 through 55 are incorporated by reference as if fully set forth herein.
- 57. The Secretary's new regulation is in clear violation of the Medicare statute at 42 U.S.C. § 1395ww(d)(5)(F)(vi) (hanging paragraph) as amended by Congress in the DRA 2005.
- 58. The Medicare statute is clear. Once the Secretary regards patients as eligible by providing coverage for their inpatient care through an approved section 1115 waiver, the Secretary must include all such patient days in the numerator of the Medicaid fraction. *Forrest General*, 926 F.3d at 228. The Secretary's new regulation defies this command. It unlawfully carves out a subpopulation of patients who receive inpatient benefits through an approved section 1115 waiver.
- 59. The consequences of this payment determination are not hypothetical. They are known and serious. Collectively, for the fourteen Plaintiff hospitals in this action, the projected loss of Medicare DSH money is over \$10.4 million per year. Beyond the unlawful loss of additional Medicare DSH reimbursement, the new regulation poses irreparable harm by jeopardizing many of the Plaintiff hospitals' ability to save millions of dollars on the costs of expensive outpatient drugs through participation in the federal 340B Drug Pricing Program. Many

of the Plaintiff hospitals use this forecast to determine whether they will meet the 11.75 percent DSH threshold to quality as a 340B covered entity (or 8 percent in the case of a rural referral center) and receive future discounts from pharmaceutical manufacturers on the purchase of outpatient drugs. 42 U.S.C. § 256b(a)(4)(L). The Health Resources & Services Administration, which administers the 340B Drug Pricing Program, relies upon the DSH percentage set forth in a provider's filed cost report to determine whether the provider qualifies for 340B discounts. By excluding days attributable to patients who receive benefits through UCC pool payments, the Secretary's regulation will require these Plaintiff hospitals to file a cost report with a lower DSH percentage than the law allows. The Secretary's new regulation would, therefore, wrongfully disqualify many of the Plaintiff hospitals and other DSH hospitals from the 340B program and deprive them of savings on their drug purchases that cannot be remediated retroactively.

60. In addition, the Secretary's new regulation is arbitrary and capricious. According to the Secretary, patients who receive inpatient benefits through an approved section 1115 UCC pool receive only a "limited benefit," which is unlike a more robust "health insurance" plan. 88 Fed. Reg. at 59,016. Even if, contrary to fact, the Secretary is correct, Congress did not authorize him to take this factor into consideration when making Medicare DSH payments. *See, e.g.*, *Bethesda Health*, 389 F. Supp. 3d at 46–47 ("[t]he statutory text does not require uninsured and underinsured patients to enroll in a health insurance plan" to be counted, noting that "[t]he government's proposed interpretation would informally add new and limiting phrases to a statute that is already clear when unadorned."); *Forrest General*, 926 F.2d at 229 (the ordinary meaning of "benefit" refers broadly to an "advantage or privilege something gives; the helpful or useful effect something has.").

61. In justifying the new regulation at 42 C.F.R. § 412.106(b)(4)(iii), the Secretary simply flouts prior contrary and binding interpretations of the very statute he believes gives him the discretion to exclude certain categories of section 1115 beneficiaries from calculating the Medicaid fraction. The Secretary's only arguments are that the courts did not in fact interpret the statute in this way (even though they did) and, alternatively, by saying the Secretary's reading of the statute is more accurate (even though it is not). 88 Fed. Reg. at 59,018–20. For these reasons, the Secretary's new DSH regulation is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

#### **COUNT THREE**

# (Provider Reimbursement Review Board Dismissal)

(Violations of the Administrative Procedure Act and Medicare Regulations)

- 62. The allegations set forth in paragraphs 1 through 61 are incorporated by reference as if fully set forth herein.
- 63. By dismissing Plaintiff hospitals' appeals after identifying alleged "factual gaps," which the Board claimed prevented it from confirming jurisdiction, the Board violated 42 C.F.R. § 405.1842(e)(3)(ii). The Board acted arbitrarily and capriciously by reaching an unreasoned decision without providing Plaintiff hospitals the right to respond. Further, the Board acted arbitrarily and capriciously by manufacturing alleged "factual gaps," which it used as a pretextual basis to dismiss Plaintiff hospitals' appeals. Both actions were taken in violation of the Board's rules and regulations which are binding upon the Board.
- 64. For the reasons explained above, the Board's dismissal was "arbitrary, capricious, an abuse of discretion ... [and] without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (D).

# VII. RELIEF REQUESTED

- 65. Plaintiff hospitals request that this Court enter an Order:
  - (a) Finding that the Plaintiff hospitals' group appeals are jurisdictionally proper and that the Board erred in dismissing the Plaintiff hospitals' group appeals;
  - (b) Retaining jurisdiction over the Plaintiff hospitals' group appeals given that a remand to the Board would be futile because the Board has no authority to hear the merits of the Plaintiff hospitals' regulatory challenges;
  - (c) Invalidating and vacating the Secretary's new regulation at 42 C.F.R. § 412.106(b)(4)(iii);
  - (d) Permanently enjoining the Secretary from applying his new regulation at 42 C.F.R. 412.106(b)(4)(iii).
  - (e) Requiring the Defendant to pay legal fees and cost of suit incurred by the Plaintiff hospitals; and
  - (f) Providing such other relief as the Court may consider appropriate.

Date: May 10, 2024 Respectfully submitted,

# /s/ Veronica Moye

Veronica Moye Texas Bar No. 24000092 3232 McKinney Avenue Suite 500 Dallas, Texas 75204

Tel: 214-450-5450 Fax: 713-751-3290 vmoye@kslaw.com

Pro Hac Vice Forthcoming

# /s/ Mark D. Polston

Mark D. Polston, D.C. Bar No. 431233 Christopher P. Kenny, D.C. Bar No. 991303 Alek Pivec, D.C. Bar No. 1046247 Ahsin Azim, D.C. Bar No. 1671019 KING & SPALDING LLP 1700 Pennsylvania Avenue, N.W. Suite 900 Washington, D.C. 20006 (202) 737-0500 (phone) (202) 626-3737 (fax) MPolston@kslaw.com

Attorneys for Plaintiffs